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Voluntary - Public

Date: 2010/05/28

GAIN Report Number: JA0016

Japan

Post: Tokyo

MRL Changes in Imibenconazole and other 5 chemicals

Report Categories:

Sanitary/Phytosanitary/Food Safety

Approved By:

Jeffrey Nawn

Prepared By:

Suguru Sato

Report Highlights:

On May 19, 2010, Government of Japan announced proposed changes to the MRLs for Imibenconazole, Flusilazole, Propamocarb, Metolachlor, Carprofen and Clenbuterol. The domestic comment period will close on June 2, 2010. After the domestic comment period closes, MHLW will then notify these proposed changes to the WTO/SPS committee, which will provide another chance for public comments to be submitted on this subject.

General Information:

Summary

On May 19, 2010, Government of Japan announced proposed changes to the MRLs for Imibenconazole, Flusilazole, Propamocarb, Metolachlor, Carprofen and Clenbuterol. The period for sending comments on these changes ends June 2, 2010. It is best to send comments directly to MHLW as soon as possible. However, MHLW will also notify these proposed changes to the WTO/SPS committee, which will provide another chance for public comments to be submitted on this subject. The actual WTO-SPS notifications can be found at the site below.

http://www.wto.org/english/tratop_e/sps_e/work_and_doc_e.htm

After the closing of the comment period in the WTO, a final report will be made based on the conclusions of a session of the Pharmaceutical Affairs and Food Sanitation Council slated to be held at a later date; this will constitute the final decision.

The comments to GOJ can be either Japanese or English.

If you have comments, please send them directly to the Japanese Government at:

Standards and Evaluation Division,

Department of Food Safety,

Pharmaceutical and Food Safety Bureau,

Ministry of Health, Labour and Welfare

1-2-2, Chiyoda-ku, Kasumigaseki, Tokyo, 100-8916

Tel: 03-5253-1111

Fax: 03-3501-4868

Pesticide

Mr. K. Shigeno (shigeno-katsushiro@mhlw.go.jp)

Dr. N. SARUTA (saruta-noriko@mhlw.go.jp)

Mr. K. ISHIDA (ishida-kazuyoshi@mhlw.go.jp)

Mr. T. SHIMIZU (shimizu-takashi01@mhlw.go.jp)

Ms. K. MIYOSHI (miyoshi-kanako@mhlw.go.jp)

Tel. ex. 2487

Veterinary drug

Mr. K. URAKAMI (uragami-kenji@mhlw.go.jp)
Mr. H. DEGUCHI (deguchi-haruyuki@mhlw.go.jp)
Mr. Y. ISHII (ishii-yasuhiroaa@mhlw.go.jp)
Tel. ex. 2489

Please also consider copying the U.S. Embassy, Tokyo at agtokyo@usda.gov on your comments in order for them to be considered as part of the official U.S. Government comments to the WTO.

Establishment of Maximum Residue Limits for Agricultural Chemicals and Veterinary Drugs in Food

Purpose and Background

The Ministry of Health, Labour and Welfare (MHLW) works to develop the compositional specification for food.

Under the provisions of Article 11, Paragraph 1 of the Food Sanitation Law, MHLW is authorized to establish residue standards (maximum residue limits: MRLs) for pesticides, feed additives, and veterinary drugs (hereafter referred to as just “agricultural chemicals”) that may remain in foods. Pursuant to these provisions, any food for which standards are established is not permitted to be marketed in Japan unless such food complies with the established standards.

On May 29, 2006, the MHLW introduced the positive list system for agricultural chemicals in food.* Basically, all foods distributed in the Japanese marketplace are subject to regulation based on this system.

At this time MHLW has newly established MRLs (draft) for some food commodities, as well as a comprehensive review of the current MRLs. This activity is targeted to six chemicals: Imibenconazole, Flusilazole, Propamocarb, Metolachlor, Carprofen, Clenbuterol. Details are given below.

Note: The positive list system was established based on the 2003 amendment of the Food Sanitation Law. The system aims to prohibit the distribution of any food in the Japanese marketplace if it contains agricultural chemicals at amounts exceeding a certain level (0.01 ppm) specified under the Law.

Outline of revision

Imibenconazole (fungicide): This chemical is already permitted for use in Japan. The MHLW has reviewed the MRLs that had been provisionally established at the time of the introduction of the new system.

Flusilazole (fungicide): This chemical is not permitted for use in Japan. This time applications have been filed by the Korean and New Zealand Governments, respectively, with the MHLW for the establishment of MRLs for the chemical, based on the Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals Used outside Japan, published on 5 February 2004. In response to these applications, the MHLW has newly established MRLs (draft) for some crops and comprehensively reviewed the existing MRLs.

Propamocarb (fungicide): This chemical is already permitted for use in Japan as an active ingredient. Currently, some forms of products using this chemical are registered. This time, in response to an application from a manufacturer, the Ministry of Agriculture, Forestry and Fisheries (MAFF) has decided to additionally permit the use of the chemical in different forms of products based on the Agricultural Chemicals Regulation Law. In step with the MAFF's action, the MHLW has newly established MRLs (draft) for some crops and comprehensively reviewed the existing MRLs.

Metolachlor (herbicide) : This chemical is already permitted for use in Japan as an active ingredient. Currently, some forms of products using this chemical are registered. This time, in response to an application from a manufacturer, MAFF has decided to additionally permit the use of the chemical in different forms of products based on the Agricultural Chemicals Regulation Law. In step with the MAFF's action, the MHLW has newly established MRLs (draft) for some crops and comprehensively reviewed the existing MRLs.

Current MRLs for **Imibenconazole**, **Flusilazole**, **Propamocarb**, and **Metolachlor** for some food commodities appear in Provisional MRLs List (Item 7, Section A). These MRLs have been modified as necessary. Finalized MRLs will be placed on the MRLs List in Item 6, and the MRLs currently placed in Item 7 will be deleted.

Carprofen (non-steroidal anti-inflammatory drug): This chemical is permitted for use in Japan. The MHLW has comprehensively reviewed MRLs that had been provisionally established at the time of the introduction of the new system.

Clenbuterol (β -adrenoceptor agonist): This chemical is permitted for use in Japan. The MHLW has comprehensively reviewed MRLs that had been provisionally established at the time of the introduction of the new system.

Current MRLs for **Carprofen** and **Clenbuterol** appear in Provisional MRLs List (Item 7, Section A). The MRLs for **Carprofen** will be withdrawn, which means that the uniform limit 0.01 ppm will be applied for all commodities after implementation of the revision of the residue standards. Clenbuterol will be newly categorized in Item 5, which specifies substances that shall not be included in food. However, MRLs are already

established for cattle and other terrestrial mammals muscle, fat, liver, kidney, other edible offal, and milk and these MRLs have been modified as necessary. Finalized MRLs will be placed in the MRLs List in item 6 and the MRLs currently placed in Item 7 will be deleted.

Imibenconazole

Commodity	MRL (draft) ppm	MRL (current) ppm
Soybeans, dry	0.3	0.5
Beans, dry (including butter beans, cowbeans (red beans), lentil, lima beans, pegia, sultani, sultapya, and white beans)		0.1
Peas		0.1
Broad beans		0.1
Peanuts, dry	0.1	0.1
Other legumes/pulses		0.1
Water melon	0.3	1
Melons	0.5	1
<i>Makuwauri</i> melon		1
<i>Unshu</i> orange, pulp	0.2	1
Citrus <i>natsudaikai</i> , whole	1	1
Lemon	1	1
Orange (including navel orange)	1	1
Grapefruit	1	1
Lime	1	1
Other citrus fruits	1	1
Apple	1	1
Japanese pear	0.3	1
Pear	0.3	1
Quince		1
Loquat		1
Peach	0.5	1
Nectarine		1
Apricot	2	5
Japanese plum (including prune)		5
Mume plum	2	2
Cherry		5
Strawberry		5
Raspberry		5
Blackberry		5
Blueberry		5
Cranberry		5
Huckleberry		5
Other berries		5
Grape	5	5
Japanese persimmon		1

Banana		1
Kiwifruit		1
Papaya		1
Avocado		1
Pineapple		1
Guava		1
Mango		1
Passion fruit		1
Date		5
Other fruits		5
Tea	15	20
Other spices	3	5

* The uniform limit 0.01 ppm is applied to commodities for which draft MRLs are not given in this table and to commodities not listed above.

* In the "Commodity" column, for the food categories to which the word *other* is added, refer to the Notes given in the last two pages of the Attachment.

Flusilazole

Commodity	MRL (draft) ppm	MRL (current) ppm
Wheat	0.2	0.1
Barley	0.2	0.1
Rye	0.2	0.1
Corn (maize, including pop corn and sweet corn)	0.01	
Buckwheat	0.2	
Other cereal grains	0.2	0.05
Soybeans, dry	0.05	
Sugar beet	0.05	0.01
Sugarcane	0.05	0.05
Other solanaceous vegetables	0.3	
Citrus <i>natsudaïdai</i> , whole	0.1	
Lemon	0.1	
Orange (including navel orange)	0.1	
Grapefruit	0.1	
Lime	0.1	
Other citrus fruits	0.1	
Apple	0.3	0.2
Japanese pear	0.3	0.2
Pear	0.3	0.2
Quince	0.3	0.2
Loquat	0.3	0.2
Peach		0.05
Nectarine	0.2	0.05

Apricot	0.2	0.05
Japanese plum (including prune)		0.05
Mume plum		0.05
Cherry		0.05
Strawberry		0.5
Grape	0.2	0.5
Banana	0.03	0.1
Sunflower seeds	0.1	0.05
Rapeseeds	0.1	0.05
Other oil seeds		0.05
Other spices		0.05
Cattle, muscle	0.1	0.01
Cattle, fat	1	
Pig, fat	1	
Cattle, liver	2	0.02
Pig, liver	2	
Cattle, kidney	2	0.02
Pig, kidney	2	
Cattle, edible offal (hereafter "edible offal" refers to all edible parts, except muscle, fat, liver, and kidney)	2	0.02
Pig, edible offal	2	
Milk	0.05	0.01
Chicken, muscle	0.2	0.01
Chicken, fat	0.2	0.01
Chicken, liver	0.2	0.01
Chicken, kidney	0.2	0.01
Chicken, edible offal	0.2	0.01
Chicken, eggs	0.1	0.01
Other poultry animals, edible offal	0.1	0.01
Raisin	0.3	1

* The uniform limit 0.01ppm is applied to commodities for which draft MRLs are not given in this table and to commodities not listed above.

* In the "Commodity" column, for the food categories to which the word *other* is added, refer to the Notes given in the last two pages of the Attachment.

Propamocarb

Commodity	MRL (draft) ppm	MRL (current) ppm
Rice (brown rice)	0.1	0.1
Potato	0.3	0.5
Sugar beet	0.2	0.2
Japanese radish, roots (including radish)	1	5.0
Chinese cabbage	10	
Cabbage	0.1	0.1
Brussels sprouts	1.0	1.0
Qing-geng-cai	0.5	0.5
Cauliflower	0.2	0.2

Broccoli	0.5	0.5
Other cruciferous vegetables	0.5	0.5
Chicory	2	1.0
Lettuce (including cos lettuce and leaf lettuce)	10	10
Onion	0.05	
Welsh (including leek)	3.0	3.0
Celery	0.2	0.2
Tomato	2	1.0
Pimiento (sweet pepper)	3	1.0
Egg plant	0.3	0.1
Other solanaceous vegetables	2	2
Cucumber (including gherkin)	5	2.0
Pumpkin (including squash)	5	0.5
Oriental pickling melon (vegetable)	5	0.5
Water melon	0.5	0.5
Melons	0.5	0.5
<i>Makuwauri</i> melon	0.5	0.5
Other cucurbitaceous vegetables	5	0.5
Spinach	40	10
Bamboo shoots	0.2	0.2
Ginger	10	10
Other vegetables	0.2	0.2
Strawberry	0.1	0.1
Other spices		0.2
Other herbs		0.5
Cattle, muscle	0.01	
Pig, muscle	0.01	
Other terrestrial mammals, muscle	0.01	
Cattle, fat	0.01	
Pig, fat	0.01	
Other terrestrial mammals, fat	0.01	
Cattle, liver	0.01	
Pig, liver	0.01	
Other terrestrial mammals, liver	0.01	
Cattle, kidney	0.01	
Pig, kidney	0.01	
Other terrestrial mammals, kidney	0.01	
Cattle, edible offal ("edible offal" refers to all edible parts, except muscle, fat, liver, and kidney)	0.01	
Pig, edible offal	0.01	
Other terrestrial mammals, edible offal	0.01	
Milk	0.01	
Chicken, muscle	0.01	
Other poultry animals, muscle	0.01	
Chicken, fat	0.01	
Other poultry animals, fat	0.01	
Chicken, eggs	0.01	
Other poultry, eggs	0.01	
Pepper, dry	10	

*The MRLs for propamocarb are the sum of propamocarb and propamocarb hydrochloride.
 * The uniform limit 0.01ppm is applied to commodities for which draft MRLs are not given in this table and to commodities not listed above.
 * In the "Commodity" column, for the food categories to which the word *other* is added, refer to the Notes given in the last two pages of the Attachment.

Metolachlor

Commodity	MRL (draft) ppm	MRL (current) ppm
Rice (brown rice)	0.1	0.1
Wheat	0.1	0.1
Barley	0.1	0.1
Rye	0.1	0.1
Corn (maize, including pop corn and sweet corn)	0.1	0.1
Buckwheat	0.1	0.1
Other cereal grains	0.3	0.3
Soybeans, dry	0.2	0.2
Beans, dry (including butter beans, cowbeans (red beans), lentil, lima beans, pegia, sultani, sultapya, and white beans.	0.2	0.3
Peas	0.3	0.3
Broad beans	0.3	0.3
Peanuts, dry	0.2	0.5
Other legumes/pulses	0.3	0.3
Potato	0.2	0.2
Taro	0.05	0.1
Sweet potato	0.1	0.1
Yam	0.02	0.1
Konjac	0.05	0.1
Other potatoes		0.1
Sugar beet	0.1	0.1
Sugarcane		0.05
Japanese radish, roots (including radish)	0.1	0.1
Japanese radish, leaves (including radish)	0.05	0.1
Turnip, roots (including rutabaga)	0.1	0.1
Turnip, leaves (including rutabaga)	0.05	0.1
Horseradish	0.3	0.1
Watercress		0.1
Chinese cabbage	0.1	0.1
Cabbage	0.05	1
Brussels sprouts	1	1
Kale		0.02
Komatsuna(Japanese mustard spinach)		0.1

<i>Kyona</i>		0.1
Qing-geng-cai		0.1
Cauliflower	0.02	0.02
Broccoli	0.02	0.02
Other cruciferous vegetables	0.1	0.1
Burdock		0.1
Salsify		0.1
Artichoke		0.1
Chicory		0.1
Endive		0.1
<i>Shungiku</i>		0.1
Lettuce (including cos lettuce and leaf lettuce)		0.1
Other composite vegetables	0.1	0.1
Onion	0.05	1
Welsh (including leek)		0.1
Garlic	1	1
<i>Nira</i>		0.1
Asparagus	0.1	0.1
Multiplying onion (including shallot)		1
Other liliaceous vegetables		0.1
Carrot	0.05	0.1
Parsnip		0.1
Parsley		0.1
Celery		0.1
<i>Mitsuba</i>		0.1
Other umbelliferous vegetables	0.1	0.1
Tomato	0.1	0.07
Pimiento (sweet pepper)	0.1	0.1
Other solanaceous vegetables	0.5	0.5
Cucumber (including gherkin)		0.05
Pumpkin (including squash)	0.05	0.05
Oriental pickling melon (vegetable)		0.05
Water melon		0.05
Melons		0.05
<i>Makuwauri</i> melon		0.05
Other cucurbitaceous vegetables		0.05
Spinach	0.3	0.3
Bamboo shoots		0.05
Ginger		0.1
Peas, immature (with pods)	0.3	0.3
Kidney beans, immature (with pods)	0.3	0.3
Green soybeans	0.3	0.3
Other vegetables	0.05	0.05
Apple	0.1	0.1
Japanese pear	0.1	0.1
Pear	0.1	0.1
Peach	0.1	0.1
Nectarine	0.1	0.1
Apricot	0.1	0.1
Japanese plum (including prune)	0.1	0.1

Mume plum	0.1	0.1
Cherry	0.1	0.1
Other fruits		0.05
Sunflower seeds	0.05	0.05
Safflower seeds	0.1	0.1
Cotton seeds	0.1	0.1
Rapeseeds	0.05	0.05
Other oil seeds		0.05
Ginkgo nut	0.1	0.1
Chestnut	0.1	0.1
Pecan	0.1	0.1
Almond	0.1	0.1
Walnut	0.1	0.1
Other nuts	0.1	0.1
Other spices		0.3
Other herbs	0.1	0.1
Cattle, muscle		0.03
Pig, muscle		0.03
Other terrestrial mammals, muscle		0.03
Cattle, fat		0.02
Pig, fat		0.02
Other terrestrial mammals, fat		0.02
Cattle, liver		0.05
Pig, liver		0.05
Other terrestrial mammals, liver		0.05
Cattle, kidney		0.2
Pig, kidney		0.1
Other terrestrial mammals, kidney		0.1
Cattle, edible offal (“edible offal” refers to all edible parts, except muscle, fat, liver, and kidney)		0.04
Pig, edible offal		0.04
Other terrestrial mammals, edible offal		0.04
Milk		0.03
Chicken, muscle		0.02
Other poultry animals, muscle		0.02
Chicken, fat		0.02
Other poultry animals, fat		0.02
Chicken, liver		0.04
Other poultry animals, liver		0.04
Chicken, kidney		0.02
Other poultry animals, kidney		0.02
Chicken, edible offal		0.02
Other poultry animals, edible offal		0.02
Chicken, eggs		0.02
Other poultry, eggs		0.02
Mineral waters (natural mineral waters and bottled/package drinking waters)		0.01

* The uniform limit 0.01ppm is applied to commodities for which draft MRLs are not given in this table and to commodities not listed above.

* In the "Commodity" column, for the food categories to which the word *other* is added, refer to the Notes given in the last two pages of the Attachment.

Calprofen

	MRL (draft) ppm	MRL (Current) ppm
	EndFragment	
Cattle, muscle		0.5
Other terrestrial mammals, muscle		0.5
Cattle, fat		1
Other terrestrial mammals, fat		1
Cattle, liver		1
Other terrestrial mammals, liver		1
Cattle, kidney		1
Other terrestrial mammals, kidney		1
Cattle, edible offal (hereafter "edible offal" refers to all edible parts, except muscle, fat, liver, and kidney)		1
Other terrestrial mammals, edible offal		

* The uniform limit 0.01ppm is applied to all commodities.

* In the "Commodity" column, for the food categories to which the word *other* is added, refer to the Notes given in the last two pages of the Attachment.

Clenbuterol

Commodity	MRL (draft) ppm	MRL (current) ppm
Cattle, muscle	0.0002	0.0002
Pig, muscle	ND	ND
Other terrestrial mammals, muscle	0.0002	0.0002
Cattle, fat	0.0002	0.0002
Pig, fat	ND	ND
Other terrestrial mammals, fat	0.0002	0.0002
Cattle, liver	0.0006	0.0006
Pig, liver	ND	ND
Other terrestrial mammals, liver	0.0006	0.0006
Cattle, kidney	0.0006	0.0006
Pig, kidney	ND	ND
Other terrestrial mammals, kidney	0.0006	0.0006

Cattle, edible offal (hereafter "edible offal" refers to all edible parts, except muscle, fat, liver, and kidney)	0.0006	0.0001
Pig, edible offal	ND	ND
Other terrestrial mammals, edible offal	0.0006	0.0001
Milk	0.00005	0.00005
Chicken, muscle	ND	ND
Other poultry animals, muscle	ND	ND
Chicken, fat	ND	ND
Other poultry animals, fat	ND	ND
Chicken, liver	ND	ND
Other poultry animals, liver	ND	ND
Chicken, kidney	ND	ND
Other poultry animals, kidney	ND	ND
Chicken, edible offal	ND	ND
Other poultry animals, edible offal	ND	ND
Chicken, eggs	ND	ND
Other poultry, eggs	ND	ND
Salmoniformes (such as salmon and trout)	ND	ND
Anguilliformes (such as eel)	ND	ND
Perciformes (such as bonito, horse mackerel, mackerel, sea bass, sea bream and tuna)	ND	ND
Other fish	ND	ND
Shelled molluscs	ND	ND
Crustaceans	ND	ND
Other aquatic animals (all aquatic animal, except fish, crustaceans and shelled molluscs)	ND	ND
Honey	ND	ND

* This compound shall not contain in commodities for which no draft MRL is given in this table or in commodities not listed above.

* In the "Commodity" column, for the food categories to which the word *other* is added, refer to the Notes given in the last two pages of the Attachment.

* ND refers to "not detected."